

09/624,855

Attorney Docket No. 6319-11

REMARKS

1. Notes

Claims 2, 4, and 6-10 are currently pending. Claim 2 is hereby amended, claims 4 and 6-10 are cancelled, and claims 17-19 are added. Upon entry of the amendments, claims 2 and 17-19 will be pending.

The pending Office Action (paper No. 14) states that it was issued in response to communications from the applicant dated June 11, 2003, and makes no reference to applicant's "Supplemental Response After Final" dated June 19, 2003. The June 19 Supplemental Response presented an amendment to claim 2, deleting "lymphocytes" and inserting "T cells". In drafting the above presentation of the instant amendments, applicant has assumed that the June 19 amendment to claim 2 was not entered. If the examiner has in fact entered the term "T cells" into claim 2, applicant respectfully requests deletion of the term.

2. The amendments

Claim 2 is amended to recite that it is directed to "A method of promoting a Type 1 response and suppressing a Type 2 response". Support is found in the body of claim 1 as originally filed. The body of the claim is amended to recite "by administering an effective amount of ribavirin to the T cells of a human in need of such promotion and suppression of T cell responses." Administration of ribavirin to the T cells is recited in claim 1 as originally filed. The phrase "a human in need of said promotion and suppression of T cell responses" is new, but does not introduce new matter.

Claims 4 and 6-10 are hereby cancelled without prejudice.

New claim 17 is dependent from claim 2. Support for the phrase "a concentration of about 0.25 – 6.7 mM in a medium supporting the T cells" is found in claim 2 as originally filed.

New claims 18 and 19 are dependent from claim 2 and claim 17, respectively. Support for the administration of interferon alpha to the patient is found in claim 4 as originally filed.

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The amendments are made in order to more clearly point out and distinctly claim the invention, and do not add new matter. Applicant reserves the right to prosecute claims to the subject matter described in the cancelled claims, in this or a continuing application.

3. Claim rejections – inherent anticipation

Claims 2, 4, and 6-10 stand rejected under 35 USC 102(b) as anticipated by Brillanti et al., *Gastroenterology* 107:812-817 (1994). Claims 4 and 6-10 are cancelled, rendering the grounds of rejection moot as to those claims.

According to the examiner, Brillanti discloses administration of ribavirin to a human in order to treat Hepatitis C. Brillanti does not disclose the modulation of Type 1 and Type 2 responses that are recited in claim 2, but the examiner regards the modulation of Type 1 and Type 2 responses as merely an effect of the administration of ribavirin, a property that is inherent to treatment with ribavirin and thus inherently anticipated by Brillanti. The examiner cites *Atlas Powder v. IRECO, Inc.*, 190 F.3d 1342 (Fed.Cir. 1999) for the proposition that “insufficient prior understanding of the inherency properties of a known composition does not defeat a finding of anticipation.”

Applicant respectfully traverses. The Federal Circuit has, in other cases, held that a prior art reference will inherently anticipate only if evidence of the inherent property “would be so recognized by persons of ordinary skill.” *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed.Cir. 1991). Thus, whether a previously-unrecognized property of a known composition constitutes inherent anticipation of a later-filed claim is a fact-dependent question that is not categorically resolved by *Atlas Powder*. For example, a new use for a known composition will often rely on an inherent property of the composition, but it is well-established that this, standing alone, presents no barrier to the patentability of method-of-use claims directed to the newly discovered utility.

4. Claim rejections – preamble as limitation.

The examiner notes that claim 2 contains preamble language setting forth an intended use, but does not consider the intended use to be a limitation on the scope of the claim that would distinguish the invention over the Brillanti reference.

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Applicant respectfully traverses, and submits that the intended use set forth in the preamble to claim 2 constitutes a limitation on the scope of the claim. This is true regardless of whether the *Atlas Powder* or *Continental Can* standard for inherent anticipation is applied.

In *Rapoport v. Dement*, 59 USPQ2d 1217 (Fed.Cir. 2001), the interference count at issue began with the preamble "A method for treatment of sleep apneas comprising administration of a therapeutically effective regimen..." The court, while recognizing that the phrase "treatment of sleep apneas" was technically part of the preamble, found that "there is no dispute in this case that the phrase should be treated as a claim limitation." *Rapoport*, 59 USPQ2d at 1219. The court also noted that the claim limitation "to a patient in need of such treatment" would not have an antecedent basis if "A method for treatment of sleep apneas" in the preamble was not also a claim limitation. (The preamble may provide a limitation if it "provides antecedents for ensuing claim terms and limits the claim accordingly." *C.R. Bard, Inc. v. M3 Systems, Inc.*, 48 USPQ2d 1225, 1231 (Fed.Cir. 1998).)

A more recent example is *Jansen v. Rexall Sundown Inc.*, 68 USPQ2d 1154 (Fed.Cir. 2003), where the preamble "A method of treating or preventing macrocytic-megaloblastic anemia in humans ..." was held to be a limitation which required that the method be practiced with the intent to achieve the objective stated in the preamble. According to the court, "The preamble is therefore not merely a statement of effect that may or may not be desired or appreciated. Rather, it is a statement of the intentional purpose for which the method must be performed." *Jansen v. Rexall*, 68 USPQ2d at 1158.

In order to further clarify the issue and help resolve the question, Applicant has amended claim 2 to parallel the construction of the claims that were at issue in *Rapoport* and *Jansen*. Applicant respectfully submits that, when the limitation provided by the claim preamble is given effect, as mandated by *Rapoport* and *Jansen*, the subject matter of claim 2 is not anticipated, either literally or inherently, by the Brillanti reference, which does not disclose the modulation of Type 1 and Type 2 responses.

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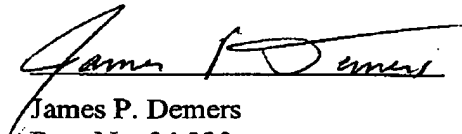
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CONCLUSION

Applicant believes that, in view of the above amendments and remarks, the grounds for rejection of claim 2 under 35 USC 102(a) in view of the *Brillanti* reference have been overcome, and withdrawal of the rejection is accordingly requested. Claim 2 having been found otherwise patentable in the Office Action dated May 20, 2003 (paper No. 11), applicant respectfully submits that claim 2 and dependent claims 17-19 are in condition for allowance.

The Examiner is invited to call Applicant's undersigned agent at the number below to resolve any remaining questions.

Respectfully submitted,


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